



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day comment request:

Women's Health Initiative Observational Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), 0020the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on February 5, 2013 on pages 8152-8153 and allowed 60-days for public comment. One comment was received and an appropriate response was made. The purpose of this notice is to allow an additional 30 days for public comment. The NHLBI, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs,

OIRA\_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project contact: Shari Eason Ludlam, Project Officer, Women's Health Initiative Program Office, 6701 Rockledge Drive, 2 Rockledge Centre, Room 9188, MSC 7913,

Bethesda, MD 20892-7936, or call (301) 402-2900 or E-mail your request, including your address to:  
ludlams@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Women's Health Initiative Observational Study. Revision- OMB No.  
0925-0414, Expiration Date: 07/31/2013. National Heart, Lung, and Blood Institute (NHLBI),  
National Institutes of Health (NIH).

Need and Use of Information Collection: This study will be used by the NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. Continuation of follow-up years for ascertainment of medical history update forms will provide essential data for outcomes assessment for this population of aging women.

OMB approval is requested for 3 years. There are no costs to respondents other than their time, which is estimated at \$308,218 for all respondents. The total estimated annualized burden hours are 14,022.

Type of Respondent*	Number of Respondents	Number of Responses per Response	Average Burden Per Response (in hours)	Total Annual Burden Hours
OS Participants	41,495	1	20/60	13,929
Next of kin	936	1	.6/60	92
Physician/Office Staff	17	1	5/60	1

\* Annual burden is placed on health care providers and respondent relatives/informants through

requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.

Dated: \_April 9, 2013\_\_\_\_\_

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Michael S. Lauer, MD., Director  
Division of Cardiovascular Sciences, NHLBI  
National Institutes of Health

Dated: April 11, 2013\_\_\_\_\_

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Lynn W. Susulske, Government Information Specialist  
Freedom of Information and Privacy Act Branch, NHLBI  
National Institutes of Health

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